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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,325	12/14/2001	Alexander MacGregor	25000.9	6736
27683	7590	06/15/2004	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,325	MACGREGOR, ALEXANDER	
	Examiner	Art Unit	
	Gollamudi S Kishore, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6-13-03 & 4-14-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1-21.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-4, 6-9 and 15-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According claim 1, the system is a 'reverse micelle' system; claims 3 and 4 however, recite 'micelles'. Furthermore, it is unclear as to what is being conveyed by 'capable of forming micelles in a fluid environment' since the examiner is not aware of any solid systems where micelles are formed. Clarification is requested.

'said amphipathic compound' in claims 6 and 9 lack an antecedent basis in claim 2; what is recited in claim 2 is 'amphipathic ionic compound'.

'active compound of a Class III biopharmaceutics classification' renders claim 7 indefinite since it is unclear as to what is included. The examiner suggests naming of the specific compounds. Also unclear is in what solvent system the compounds exhibit high solubility. What is being conveyed by low permeability? Permeability where?

Claim 8 recites 'agent of interest' and refers back to claim 2. Claim 2 recites two agents of interest. Which is being referred to in claim 8?

Claim 15 recites several agents of interest; inclusion of 'urinary', 'vaginal' is improper since these are not active agents.

'type' in claim 16 is indefinite; the examiner suggests rewording 'matrix-type solid compact' and matrix type extrusion spheroid.

Also claims 16-18 recite solid systems whereas the parent claim 1 recites 'micelle system'. Aren't micelle systems suspensions in nature?

3. Claim 19 provides for the use of the delivery system of claim 2, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-9, 13-15 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans (5,292,499).

Evans discloses medical formulations containing reverse micelles. The surfactants include amphipathic surfactants such as phosphatidylethanolamine (cationic) and phosphatidic acid (anionic). The active agents include anti-inflammatory steroid and others (abstract, col. 6, lines 57-66; col. 7, lines 11-61; Examples and claims). Instant claims do not specify what the polar agent of interest is and therefore, any of the active agents taught by Evans, which are polar, and water would fall under this category. In the absence of showing otherwise, it is deemed that the active agents disclosed by Evans would meet the requirements of instant claims 5, 7 and 8. Since the aerosol administration is done through the mouth, the reference meets the requirements of claim 21.

6. Claims 1-6, 8-11, 13-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Linehan (5,770,172).

Linehan teaches reverse micellar systems. The surfactants taught are either cationic or anionic in nature. These include didodecyldimethylammonium bromide and sodium bis (2-ethylhexyl) sulfosuccinate) in amounts of 1-30 %. The reverse micelles contain metal compounds, which are electrolytes (abstract, col.4, line 14 through col. 5, line 9, examples and claims).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-2, 5-7, 12-14 and 16-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu (6,316,497).

Liu discloses reverse micelles containing an anti-cancer agent. The preparations are either in liquid form or various solid forms (powders) and encapsulated in a gelatin capsule (abstract, col. 3, line 58 through col. 6, line 19; Table 1; col. 6, line 63 through col. 7, line 62; Examples and claims).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 5-7, 9-10, 13-15 and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Monahan (6,429,200).

Monahan discloses reverse micelles for the delivery of nucleic acids, pharmaceuticals, proteins, peptides and hormones. The compositions include surfactants, which are either neutral, anionic or Zwitter ionic and include Tritons, tweens and sodium didecyl sulphate (abstract, col. 4, line 61 through col. 8, line 39; col. 10, lines 52-56; Examples and claims).

The references of Carlsson, Vasudevan, Owen Backlund, and McCoy are cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK